General

Guideline Title

HRS/ACCF expert consensus statement on pacemaker device and mode selection.

Bibliographic Source(s)

Gillis AM, Russo AM, Ellenbogen KA, Swerdlow CD, Olshansky B, Al-Khatib SM, Beshai JF, McComb JM, Nielsen JC, Philpott JM, Shen WK. HRS/ACCF expert consensus statement on pacemaker device and mode selection. Heart Rhythm. 2012 Aug;9(8):1344-65. [133 references] PubMed

Guideline Status

This is the current release of the guideline.

Recommendations

Major Recommendations

Classification of recommendations (I, IIa, IIb, and III) and levels of evidence (A-C) are defined at the end of the "Major Recommendations" field.

Consensus recommendations for device and mode selection apply to situations where the clinical decision for pacing has already been made.

Sinus Node Dysfunction

Class I

1. Dual-chamber pacing (DDD) or single-chamber atrial pacing (AAI) is recommended over single-chamber ventricular pacing (VVI) in patients with sinus node dysfunction (SND) and intact atrioventricular (AV) conduction (Level of Evidence: A).
2. Dual-chamber pacing is recommended over single-chamber atrial pacing in patients with SND (Level of Evidence: B).

Class IIa

1. Rate adaptive pacing can be useful in patients with significant symptomatic chronotropic incompetence and its need should be reevaluated during follow-up (Level of Evidence: C).
2. In patients with SND and intact AV conduction, programming dual-chamber pacemakers to minimize ventricular pacing can be useful for prevention of atrial fibrillation (AF) (Level of Evidence: B)

Class IIb

1. AAI pacing may be considered in selected patients with normal AV and ventricular conduction (Level of Evidence B).

2. Single-chamber VVI pacing may be considered in instances where frequent pacing is not expected or the patient has significant comorbidities that are likely to influence survival and clinical outcomes (Level of Evidence: C).

Class III

1. Dual-chamber pacing or single-chamber atrial pacing should not be used in patients in permanent or longstanding persistent AF in whom efforts to restore or maintain sinus rhythm are not planned (Level of Evidence: C).

AV Node Disease

Class I

1. Dual-chamber pacing is recommended in patients with AV block (Level of Evidence: C).
2. Single-chamber ventricular pacing is recommended as an acceptable alternative to dual-chamber pacing in patients with AV block who have specific clinical situations that limit the benefits of dual-chamber pacing. These include, but are not limited to, sedentary patients, those with significant medical comorbidities likely to impact clinical outcomes, and those in whom technical issues, such as vascular access limitations, preclude or increase the risk of placing an atrial lead (Level of Evidence: B).
3. Dual-chamber pacing is recommended over single-chamber ventricular pacing in adult patients with AV block who have documented pacemaker syndrome (Level of Evidence: B).

Class IIa

1. Single-lead, dual-chamber VDD pacing can be useful in patients with normal sinus node function and AV block (e.g., the younger patient with congenital AV block) (Level of Evidence: C).
2. VVI pacing can be useful in patients following AV junction ablation, or in whom AV junction ablation is planned, for rate control of AF due to the high rate of progression to permanent AF (Level of Evidence: B).

Class III

1. Dual-chamber pacing should not be used in patients with AV block in permanent or longstanding persistent AF in whom efforts to restore or maintain sinus rhythm are not planned (Level of Evidence: C).

Hypersensitive Carotid Sinus Syndrome

Class IIa

1. Dual-chamber or single-chamber ventricular pacing can be useful for patients with hypersensitive carotid sinus syndrome (Level of Evidence: C).

Class III

1. Single-chamber AAI pacing is not recommended for patients with hypersensitive carotid sinus syndrome (Level of Evidence: C).

Neurocardiogenic Syncope

Class IIa

1. Dual-chamber pacing can be useful for neurocardiogenic syncope (Level of Evidence: C).

Class III

1. Single-chamber AAI pacing is not recommended for neurocardiogenic syncope (Level of Evidence: C).

Long QT

Class I

1. Dual-chamber or atrial pacing compared to ventricular pacing is recommended for symptomatic or high-risk patients with congenital long QT syndrome (Level of Evidence: C).

Hypertrophic Cardiomyopathy

Class IIa

1. Dual-chamber pacing can be useful for patients with medically refractory, symptomatic hypertrophic, cardiomyopathy with significant resting, or provoked left ventricular outflow obstruction (Level of Evidence: C).

Class III

1. Single-chamber (VVI or AAI) pacing is not recommended for patients with medically refractory, symptomatic hypertrophic cardiomyopathy (Level of Evidence: C).

Definitions:

Classification of Recommendations

Class I: Conditions for which there is evidence and/or general agreement that a given pacing mode is beneficial, useful, and effective.

Class II: Conditions for which there is conflicting evidence and/or divergence of opinion about the usefulness/efficacy of a specific pacing mode.

Class IIa: Weight of evidence/opinion is in favor of usefulness/efficacy.

Class IIb: Usefulness/efficacy is less well established by evidence/opinion.

Class III: Conditions for which there is conflicting evidence and/or general agreement that a pacing mode is not useful/effective and in some cases may be harmful.

Level of Evidence

Level of Evidence A: Data derived from multiple randomized clinical trials or meta-analyses.

Level of Evidence B: Data derived from a single randomized trial or nonrandomized studies.

Level of Evidence C: Only consensus opinion of experts, case studies, or standard of care.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Conditions requiring implantation of a cardiac pacemaker including:

- Sinus node dysfunction
- Atrioventricular (AV) node disease (AV block)
- Hypersensitive carotid sinus syndrome
- Neurocardiogenic syncope
- Long QT syndrome
- Hypertrophic cardiomyopathy

Guideline Category

Evaluation

Management

Prevention

Treatment

Clinical Specialty

Cardiology

Family Practice

Internal Medicine

Thoracic Surgery

Intended Users

Advanced Practice Nurses

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To provide a state-of-the-art review of the field and to report the recommendations of a consensus writing group on pacemaker device and mode selection

Target Population

Adults who require implantation of a cardiac pacemaker

Note: This document focuses on pacemaker device and mode selection in the adult patient; therefore, many of the recommendations may not be applicable to unique situations encountered in the pediatric population.

Interventions and Practices Considered

1. Dual-chamber pacing (DDD)
2. Single-chamber atrial pacing (AAI)
3. Single-chamber ventricular pacing (VVI)

Major Outcomes Considered

- Effectiveness of pacemaker device, as assessed by major cardiovascular outcomes including mortality, stroke/thromboembolism, heart failure or hospitalization for heart failure, and atrial fibrillation
- Incidence of pacemaker syndrome
- Incidence and severity of right ventricular pacing
- Quality of life
- Functional status
- Complications related to pacing
- Cost-effectiveness

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

The Medline and PubMed databases were searched. An initial literature search was performed in November of 2011 at the time the document writing committee was initiated. Subsequent literature searches were performed as needed throughout document development and concluded in May of 2012. All randomized and observational studies in humans were included in literature searches. Initial search terms of pacemaker, pacemaker single chamber, pacemaker dual chamber, pacemaker mode selection, pacemaker DDD versus VVIR, pacemaker implantation were used; each section author was responsible for adding search criteria relevant to their section.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Level of Evidence

Level of Evidence A: Data derived from multiple randomized clinical trials or meta-analyses.

Level of Evidence B: Data derived from a single randomized trial or nonrandomized studies.

Level of Evidence C: Only consensus opinion of experts, case studies, or standard of care.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review

Description of the Methods Used to Analyze the Evidence

The writing group was divided into three subgroups to review aspects of pacing mode selection for patients with (1) sinus node dysfunction, (2) atrioventricular conduction block, and (3) other less common indications for pacing.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

These recommendations summarize the opinion of the consensus writing group, based on an extensive literature review as well as their own experience. All recommendations provided were agreed upon by at least 81% of the writing committee by anonymous vote. Writing group members were selected by the Heart Rhythm Society or the American College of Cardiology Foundation (ACCF) based on their expertise in the field. The 11 participating cardiac electrophysiologists or surgeons include representatives from the United States, Canada, and Europe.

The grading system for class of indication and level of evidence was adapted from that used by the ACCF and the American Heart Association. It is important to state that this document is not a guideline. Nevertheless, recommendations are presented with class and level of evidence designations to provide consistency with familiar guideline documents.

Values and Preferences

Similar to guideline documents, this consensus document uses a grading system that separates the quality of evidence from the strength of recommendations. This document considers factors that impact on the quality of life and functional status, such as pacemaker syndrome, right ventricular pacing, and atrial fibrillation (AF) while noting how these factors may influence mode selection. It is recognized that in addition to the quality of the evidence, several other factors might affect the class of recommendations. These factors are not represented in the official recommendations as the current class of recommendations focuses largely on scientific evidence. Alternate grading systems may consider the balance between desirable and undesirable effects of a therapy, patient and physician values, and preferences in the provision of clinical care, as well as cost of therapy for determining the strength of recommendations.

In arriving at the recommendations, the writing group considered factors such as the desirable effect of atrioventricular (AV) sequential pacing to prevent AF and the undesirable effects of ventricular pacing to cause pacemaker syndrome or promote AF. The writing group considered the values and preferences of patients to avoid AF or pacemaker syndrome. They also present examples where patient conditions influence decision of pacing mode. For instance, a young active patient who has sinus node dysfunction (SND) and normal AV and ventricular conduction may elect a single-chamber atrial (AAI) pacemaker to minimize hardware and reduce the risk of complications. Or a sedentary patient with prostate carcinoma and SND who has syncope with prolonged pauses and subclavian venous stenosis with limited venous access may accept single-chamber backup pacing rather than undergo a more complex procedure to allow insertion of a second lead.

Rating Scheme for the Strength of the Recommendations

Classification of Recommendations

Class I: Conditions for which there is evidence and/or general agreement that a given pacing mode is beneficial, useful, and effective.

Class II: Conditions for which there is conflicting evidence and/or divergence of opinion about the usefulness/efficacy of a specific pacing mode.

Class IIa: Weight of evidence/opinion is in favor of usefulness/efficacy.

Class IIb: Usefulness/efficacy is less well established by evidence/opinion.

Class III: Conditions for which there is conflicting evidence and/or general agreement that a pacing mode is not useful/effective and in some cases may be harmful.

Cost Analysis

Cost and Cost-Effectiveness of Dual- vs Single-Chamber Pacemakers

Initial hospitalization costs are higher for dual- vs single-chamber pacemakers, primarily because of the more expensive pulse generator and additional lead and the potential for higher rates of complications associated with dual-chamber pacemakers that are largely driven by atrial lead dislodgement. The reported differential initial cost between the two systems is in the range of $2200–$2600. Indeed, several studies have assessed the economic implications of implanting a ventricular or dual-chamber pacemaker in patients with sinus node dysfunction (SND) and atrioventricular (AV) block. Instead of just examining the absolute difference in cost between the two systems, these studies present cost-effectiveness analyses that also take into account differences in effectiveness between the two systems and, in some cases, adjust the results for quality of life. Indeed, such analyses are affected by many factors, including whether all important and relevant costs and effects are included, the perspective from which the costs and benefits are to be considered, whether direct and indirect costs are accounted for, the length of follow-up, and the method used to adjust the results for time. Differences in any of these factors may lead to different results.

In one analysis conducted by the Italian government, the incremental cost-effectiveness ratio of implanting a dual vs a ventricular device was 260 Euros/quality-adjusted life year (QALY) (approximately US $330/QALY). Importantly, device replacement rates due to pacemaker syndrome had the biggest impact on the final results. Thus, the higher initial costs of the dual-chamber device implants appeared to be offset by a reduction in costs associated with repeat procedures and treatment of AF. Another study conducted in the United Kingdom examined the health and economic consequences of implanting a dual-chamber versus a ventricular pacemaker for SND or AV block. That study demonstrated that the additional health benefits from dual-chamber pacing are achieved at a mean net cost of £43 per patient, resulting in a cost-effectiveness ratio of £477/QALY

(approximately US $739/QALY). Therefore, although implanting a dual-chamber device increases the cost of the initial procedure, this is expected to be counterbalanced by a reduction in costs associated with repeat procedures and the management of atrial fibrillation.

In the Canadian Trial of Physiologic Pacing, the incremental cost-effectiveness of physiological pacing was estimated from the viewpoint of a provincial government health care payer. The incremental cost-effectiveness of dual-chamber pacemakers was CAN $297,600 per life year gained (approximately US $290,482) and CAN $74,000 per AF event avoided approximately US $72,230). Based on only mortality and prevention of AF (and not considering pacemaker syndrome and quality of life), physiological pacing did not appear to be economically attractive in the short term; however, long-term studies incorporating all nonfatal cardiac events, pacemaker syndrome, and quality of life may provide a more accurate assessment of the cost-effectiveness of physiological pacing.

Using a Markov model, a cost-effectiveness analysis of the Mode Selection Trial showed that during the first 4 years, dual-chamber pacemakers increased quality-adjusted life expectancy by 0.013 year per subject with an incremental cost-effectiveness ratio of $53,000/QALY gained. Over a lifetime, dual-chamber pacing was projected to increase quality-adjusted life expectancy by 0.14 year with an incremental cost-effectiveness ratio of about $6800/QALY gained. Thus, this analysis demonstrated that for patients with SND, dual-chamber pacing increases quality-adjusted life expectancy at a cost that is generally considered acceptable.

Although not specifically examined in these cost–benefit analyses, it is anticipated that battery technology as well as device programming will also impact on cost-effectiveness. Regardless of whether single- or dual-chamber devices are selected, programming should be optimized to enhance battery longevity and reduce cost.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

The Consensus Statement was approved by the Heart Rhythm Society Board of Trustees, the American College of Cardiology Foundation Board of Trustees, the Society of Thoracic Surgeons, and the American Heart Association Science Advisory and Coordinating Committee in June of 2012.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

- Appropriate pacemaker device and mode selection in patients requiring pacemaker implantation
- Patients with sinus node dysfunction may derive benefit from atrial or dual-chamber pacing compared with ventricular pacing with regard to the risks of atrial fibrillation (AF), stroke, pacemaker syndrome, and improved quality of life. Over the long term, dual-chamber pacing may be cost-effective. In patients with atrioventricular (AV) block, although dual-chamber pacing compared to ventricular pacing has equivalent effects on major cardiovascular outcomes including mortality, stroke, heart failure, and AF, it can reduce the incidence of pacemaker syndrome and improve some indexes of quality of life.

Potential Harms

- Implant complications, including:
  - Pneumothorax
  - Hemorrhage
  - Inadequate pacing
  - Inadequate sensing
  - Device malfunctioning
  - Lead dislodgement
- Pacemaker syndrome is the occurrence of overt symptoms, such as fatigue, chest discomfort, dyspnea, cough, confusion, presyncope, or syncope due to adverse hemodynamics that result from loss of atrioventricular (AV) synchrony and occurrence of ventriculoatrial conduction or atrial contraction against closed AV valves in patients with an implanted pacemaker.
- There is strong evidence that a high proportion of right ventricular pacing, particularly in patients with some degree of left ventricular systolic dysfunction, is detrimental, and every attempt should be made to minimize it. Although pacemaker syndrome may occur with any mode of pacing, it is most common with ventricular pacing in the single-chamber ventricular pacing (VVI) mode in patients who are in sinus rhythm.
- Upgrading a device can be technically challenging and is associated with an increased risk of complications. The higher rate of initial implant complications for dual-chamber pacemakers is offset by the subsequent need to insert an atrial lead in some patients with single-chamber pacemakers during follow-up.

See section 4 of the original consensus document for additional details on complications related to pacing.

Qualifying Statements

Qualifying Statements

- It is important to state that this consensus document is not a guideline.
- This document focuses on pacemaker device and mode selection in the adult patient; therefore, many of the recommendations may not be applicable to unique situations encountered in the pediatric population.
- The original consensus document should be used as a supplement to the published 2008 guidelines document, functioning as a guide to facilitate the selection of single- vs dual-chamber devices for patients who already meet guidelines for pacemaker implantation. It should be emphasized that recommendations for device selection in the current document apply to situations where the clinical decision for pacing has already been made.
- Guideline documents and consensus statements should be used to assist health care providers in clinical decision-making by describing generally accepted approaches for patient management based on review of the literature and a consensus from experts. However, as in all such documents, "the ultimate judgment regarding care of a particular patient must be made by the health care provider and the patient in light of all of the circumstances presented by that patient." It is acknowledged that there will be circumstances in which deviations from guidelines or consensus recommendations are appropriate.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

Staying Healthy

IOM Domain

Effectiveness

Identifying Information and Availability

Bibliographic Source(s)

Gillis AM, Russo AM, Ellenbogen KA, Swerdlow CD, Olshansky B, Al-Khatib SM, Beshai JF, McComb JM, Nielsen JC, Philpott JM, Shen WK. HRS/ACCF expert consensus statement on pacemaker device and mode selection. Heart Rhythm. 2012 Aug;9(8):1344-65. [133 references] PubMed

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2012 Aug

Guideline Developer(s)

American College of Cardiology Foundation - Medical Specialty Society

Heart Rhythm Society - Professional Association

Source(s) of Funding

Heart Rhythm Society

Guideline Committee

Writing Group

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Financial Disclosures/Conflicts of Interest

All members of the writing group, as well as peer reviewers of the document, provided disclosure statements for all relationships that might be perceived as real or potential conflicts of interest. These tables are shown at the end of the original consensus document.

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: Available from the Heart Rhythm Society (HRS) Web site .

Availability of Companion Documents

The following is available:

- The HRS policy for development and endorsement of clinical guidance documents from HRS and others. Washington (DC): Heart Rhythm Society (HRS); 2009 Sep. 6 p. Available from the Heart Rhythm Society Web site .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on February 13, 2013.

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Readers with questions regarding guideline content are directed to contact the guideline developer.